



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 123

[Docket No. FDA-2013-D-0269]

Guidance for Industry on Purchasing Reef Fish Species Associated with the Hazard of Ciguatera Fish Poisoning; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled “Guidance for Industry: Purchasing Reef Fish Species Associated with the Hazard of Ciguatera Fish Poisoning.” The document provides guidance to primary seafood processors who purchase reef fish on how to minimize the risk of ciguatera fish poisoning (CFP) from fish that they distribute. The guidance intends to help protect the public health by reducing the risk of CFP.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to Division of Seafood Safety/Office of Food Safety, Center for Food Safety and Applied Nutrition, (HFS-325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the

SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Karen Swajian, Division of Seafood Safety, Center for Food Safety and Applied Nutrition (HFS-325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2300.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

We are announcing the availability of a guidance for industry entitled “Guidance for Industry: Purchasing Reef Fish Species Associated with the Hazard of Ciguatera Fish Poisoning.” This guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

In the Federal Register of March 26, 2013 (78 FR 18273), FDA made available a draft guidance entitled “Guidance for Industry: Purchasing Reef Fish Species Associated with the Hazard of Ciguatera Fish Poisoning” and gave interested parties an opportunity to submit comments by May 28, 2013, for us to consider before beginning work on the final version of the guidance. We received three comments on the draft guidance, but the comments did not prompt us to revise the guidance. Therefore, we are issuing the guidance with minor changes (revising dates mentioned in the guidance to reflect the most current information). The guidance announced in this notice finalizes the draft guidance dated March 2013.

## II. Comments

Interested persons may submit either electronic comments regarding the guidance to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## III. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: November 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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